(12) UK Patent Application (19) GB (11) 2 169 512 A

(43) Application published 16 Jul 1986

(21) Application No 8500606

(22) Date of filing 10 Jan 1985

(51) INT CL[4]
A61F 2/30 2/38

(52) Domestic classification (Edition H)
A5R AJ

(56) Documents cited
GB A 2039220 GB 1479693
GB 1575473

(58) Field of search
A5R

(71) Applicant
The Secretary of State for Trade & Industry (United Kingdom),
1 Victoria Street, London SW1H 0ET

(72) Inventor
Geoffrey David Scowen

(74) Agent and/or address for service
D. B. Wildman, Procurement Executive, Ministry of Defence, Patents 1A(4), Room 2014, Empress State Building, Lillie Road, London, SW6 1TR

(54) **Joint prosthesis**

(57) A joint prosthesis comprises first and second connecting means by which the joint can be rigidly attached to natural bones. The connecting means are joined together by a flexible element formed of fibre reinforced elastomer.

The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

GB 2 169 512 A

Fig. 1.

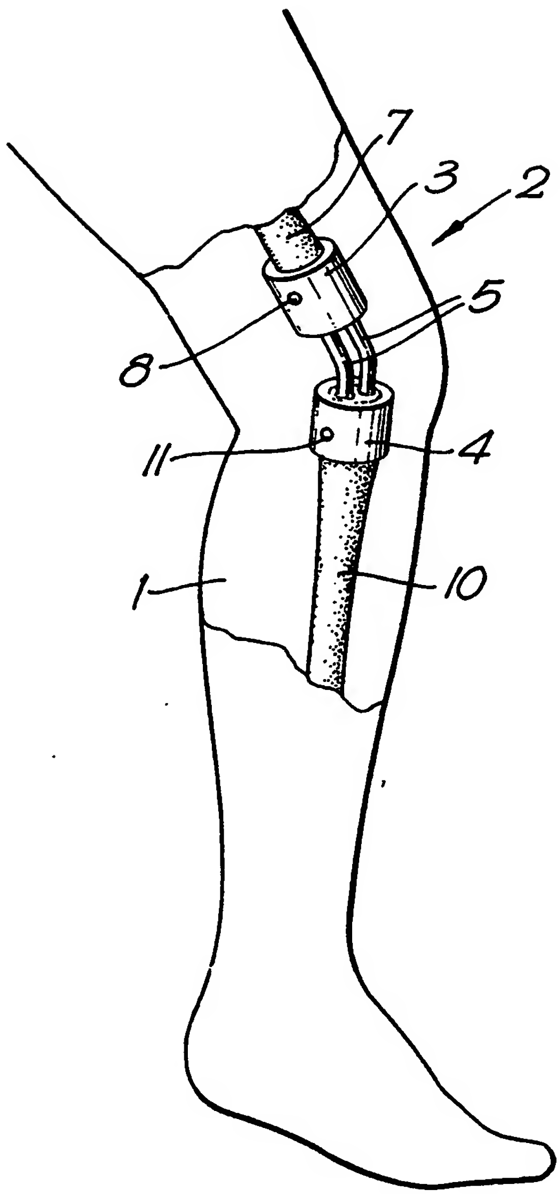



Fig. 2.

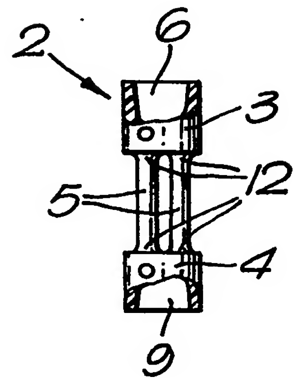


Fig.3.

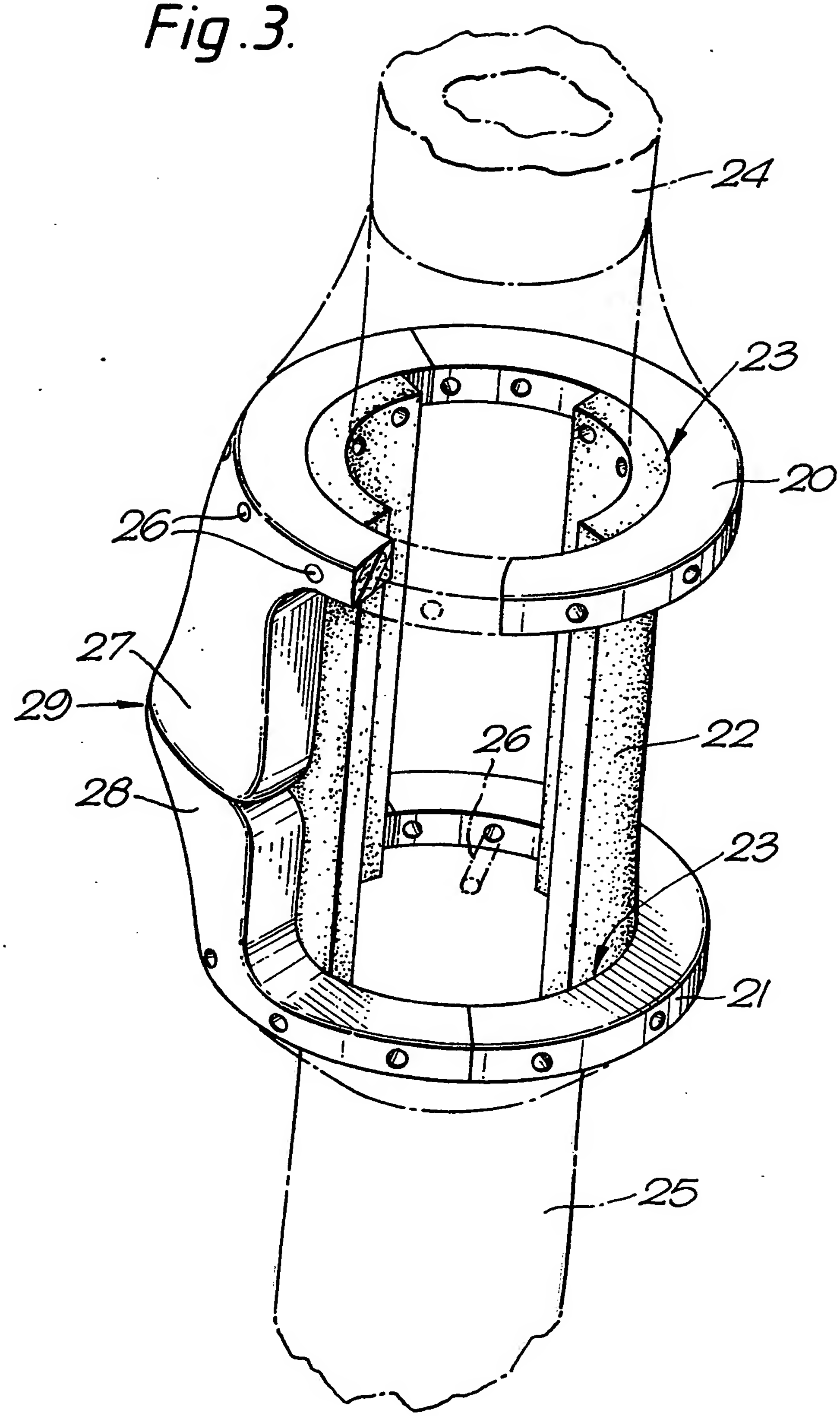
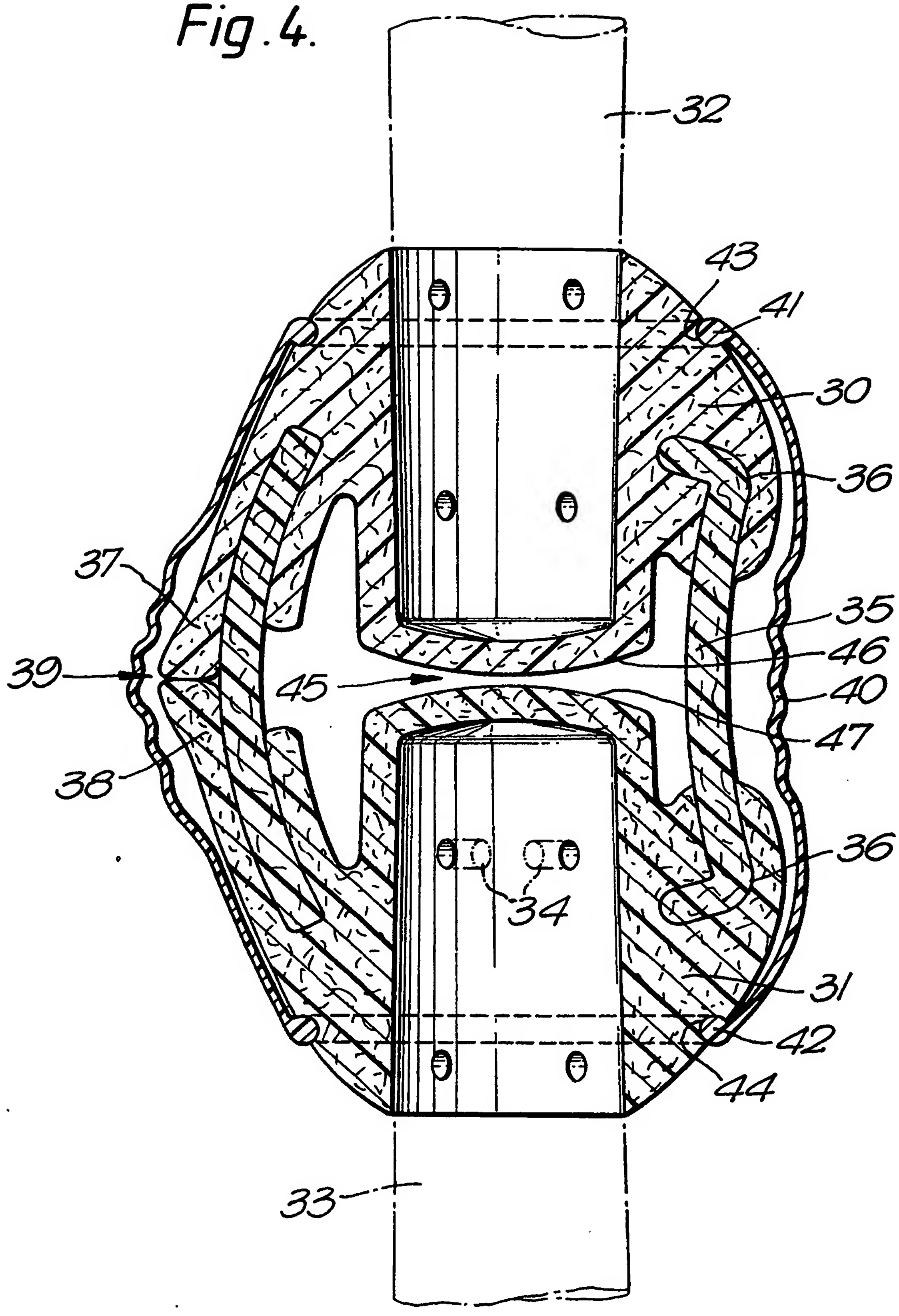


Fig. 4.



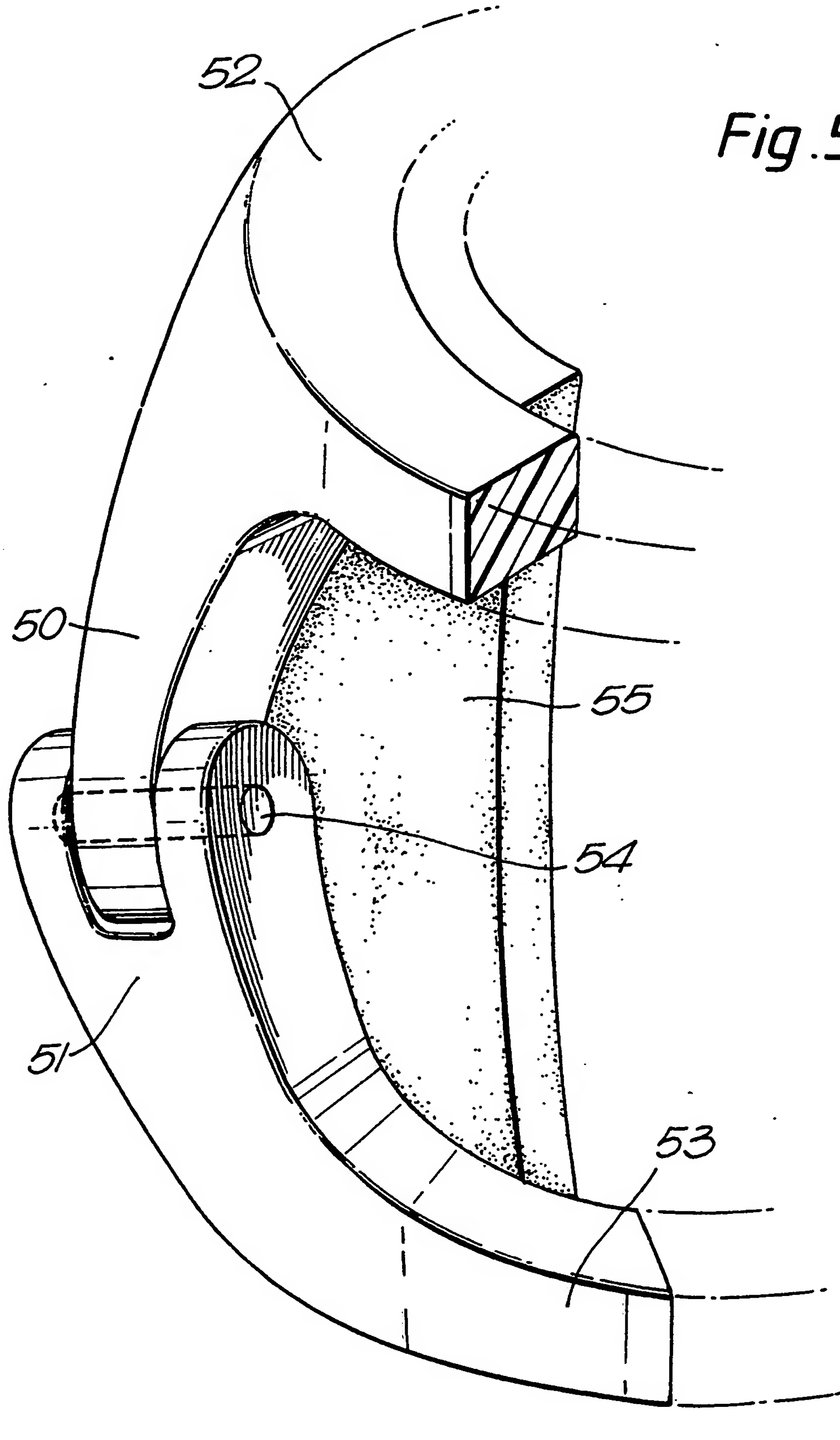



Fig.5.

Fig.6.

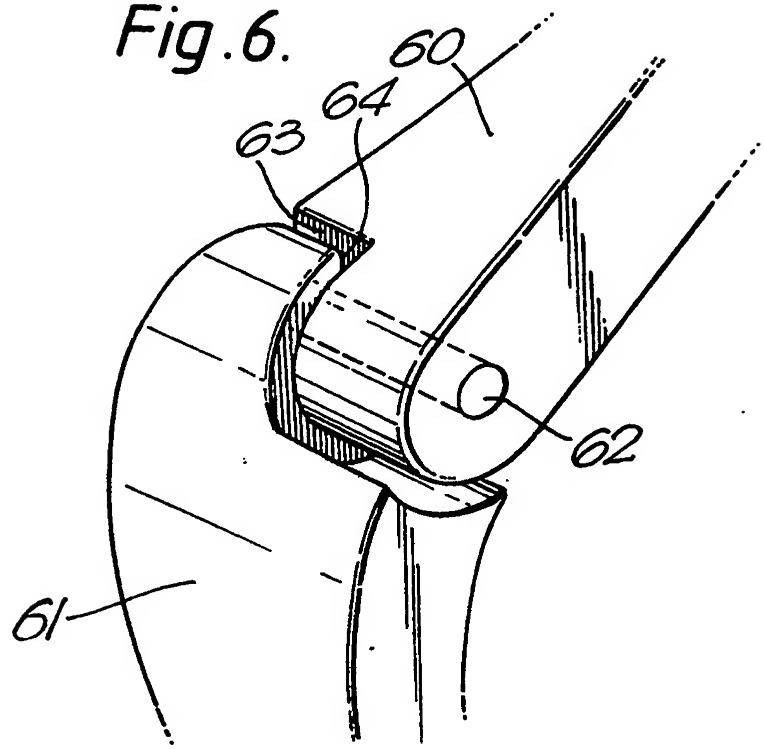
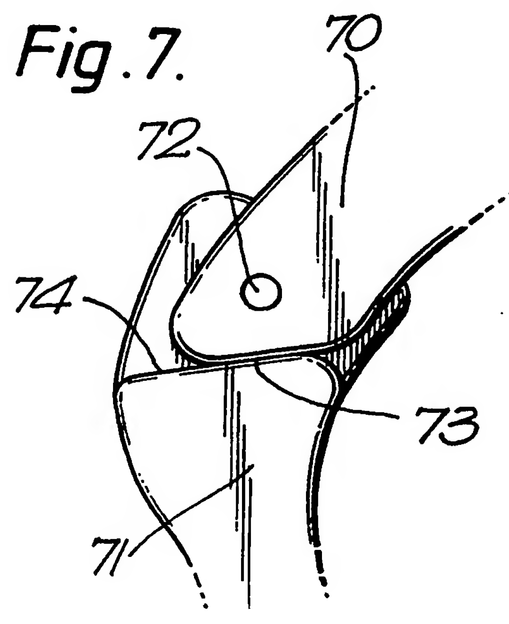



Fig.7.



SPECIFICATION
**Joint prosthesis**

This invention concerns a prosthesis joint, and especially to a human knee prosthesis.

Conventional joint prosthesis include some form of mechanical pivot arrangement, usually of a steel alloy, which over a long period of time is subject to corrosion and wear. Replacement of such a joint requires severe surgery, and is therefore highly undesirable. The present invention seeks to eliminate the need for a conventional mechanical pivot, or at least to eliminate the need for such a pivot to carry any substantial proportion of the load transmitted through the joint.

Accordingly the present invention provides a joint prosthesis comprising first and second connecting means by which the joint can be rigidly attached to the natural bones which are to be connected by the joint prosthesis, the first and second connecting means being joined together by a flexible element formed of fibre reinforced elastomer.

The connecting means may each be provided with a socket adapted to receive the end of the natural bone.

In use, the bone may be held firmly in position in the socket by use of pins passing transversely through the socket into the bone.

The connecting means are advantageously of a relatively stiff polymeric material.

Preferably the elastomer of the flexible element and the polymeric material of the connecting means are co-polymerised within transition regions linking these components.

This provides a chemical bond between the two materials, and a graded transition from one material to the other. The bond can thus be extremely strong, and the absence of an abrupt transition leads to efficient load transfer and more even stress distribution in the transition regions. Crock formation and propagation is thus inhibited, and fracture toughness is increased.

The polymeric material may itself incorporate reinforcing fibres, and in this case it is important to arrange for continuity of the fibre reinforcement from the flexible element into the connecting means.

Any combination of elastomeric material and polymeric material can be used, provided that they are mutually compatible, and capable of co-polymerisation. By co-polymerisation is meant that by an appropriate curing process the two materials form a chemically cross-linked structure in the transition region, within which molecules of the elastomeric material combine chemically with molecules of the polymeric material of the connecting means.

Suitable elastomeric materials include polyurethanes silicone elastomers, natural rubber, polyisoprene, styrene butadiene, butadiene, polyacrylics, isobutene isoprene (butyl rubber), chloroprene (neoprene), nitrile butadiene, chlorosulphonated polyethylene, chlorinated polyethylene, ethylene propylene fluorocarbons, epichlorohydrin, fluorosilicones, co-polyesters, styrene co-polymers and olefins.

Suitable polymeric materials for the connecting means are stiffer than the elastomeric material, and include epoxy resins, polyester resins, phenolic resins, vinyl esters, polyamides, and polyimides.

One combination which has been found particularly effective is a polyurethane as the elastomeric material together with an epoxy resin material for the connecting means.

Suitable fibres for reinforcement of the elastomer and/or the polymeric material of the connecting means are those which are compatible with the respective matrix in which they are incorporated, and include fibres of carbon, boron, glass, nylon, polyester, polyimides, aromatic polyamides, (e.g. Kevlar—Trade Mark), metals and mixtures of fibres of these materials.

Further aspects of such co-polymerised materials are described in my co-pending International Patent Application No: PCT/GB84/00214.

The connecting means may be provided with co-operating detent portions which interact so as to limit the angle through which the joint can be flexed in one or more directions.

Locating means may also be provided so as to ensure proper registration between the co-operating detent portions.

The orientation of the fibres, especially within the elastomer of the flexible element, is an exceedingly important matter.

Generally speaking, a high proportion of fibres should be aligned in the longitudinal direction, i.e. in the line of load transfer through the joint from one connection means to the other. This provides compressive strength and high axial stiffness for load transfer.

It is also important to provide a proportion of fibres aligned at a substantial angle to the longitudinal axis, e.g. at angles in the range ±30 to ±60°, e.g. ±45°. This can be done by braiding or filament winding techniques, for example, and provides strong resistance to undesired twisting of the joint.

The invention will now be described by way of example only with reference to the accompanying drawings, of which

Figure 1 illustrates the principle of the invention in its application to a human knee joint prosthesis;

Figure 2 shows further detail of the joint shown in Figure 1;

Figures 3 and 4 show respectively a second form and a third form of human knee joint prosthesis; and

Figures 5, 6 and 7 show details of detent means for limiting the angle of flexure of joints in accordance with the invention, and locating means to ensure proper registration of the detent means.

As shown schematically in Figures 1 and 2, a human leg 1 is fitted with a prosthesis knee joint 2 comprising first and second connecting means 3, 4 and joined together by two discrete flexible elements 5.

The connecting portions 3, 4 are formed of an epoxide material reinforced with carbon fibre. The first connecting means 3 is formed with a socket 6 adapted to receive the femur 7 which is held in place thereby by means of a stainless steel pin 8 passing transversely through the walls of the socket and

through the bone. The second connecting means 4 is formed with a socket 9 adapted to receive the tibia 10 which is similarly held in place therein by means of a stainless steel pin 11.

The flexible elements 5 are formed of a carbon fibre-reinforced polyurethane elastomer. About 60% by weight of the fibres are aligned in the longitudinal direction, i.e. in the direction of linear load transfer through the flexible elements from one connecting means to the other, so as to resist compressive axial loading, and consequent buckling. The remaining 40% of fibres are braided or filament wound at ±45° to the longitudinal axis, so as to provide resistance against twisting of the joint. As illustrated, the joint 2 is fitted to the leg in such a way that the two flexible elements 5 are located one on each side of the knee. Normal forward and rearward bending of the knee joint is thus facilitated, but with strong resistance against unnatural sideways bending of the knee. It is also highly desirable to provide means (not shown) to prevent unnatural forward bending of the joint, beyond the approximate leg straight position.

In order to give the joint a high degree of integrity and resistance to fracture between the flexible elements 5 and the connecting means 3, 4, the carbon fibre reinforcement is made continuous from the flexible elements into the connecting means. Additionally, the polyurethane of the flexible elements 5 and the epoxy resin of the connecting means 3, 4 are co-polymerized within the transition regions 12 linking these components. The materials thus form a chemically cross-linked structure in the transition regions, where molecules of the polyurethane combine chemically with molecules of the epoxy resin material.

In Figure 3 there is shown a somewhat more practical form of prosthetic joint for a human knee. The joint comprises connecting means 20, 21 each of carbon fibre reinforced epoxy resin, joined together by a flexible element 22 of essentially tubular form (shown partially cut away). The flexible element 22 is of carbon fibre reinforced polyurethane resin co-polymerised with the epoxy resin connecting means in the annular transition regions 23. As in the example of Figures 1 and 2, the carbon fibres extend continuously from the flexible element 22 through the transition regions into the connecting means, and within the flexible element there is a similar combination of longitudinal and angled fibres. The connecting means 20, 21 are formed with sockets 22, 23 for receiving respectively the femur 24 and tibia 25, which are held firmly in place by means of a plurality of stainless steel pins 26 extending through the walls of these sockets into the natural bone.

At the front of the joint the connecting means 20, 21 are formed with extensions 27, 28 which come together at 29 when the joint is straightened. These extensions act as co-operating detent portions which interact so as to limit the angle through which the joints can be flexed, i.e. they come together to prevent the knee bending forward beyond the straightened position. Elastomer may be provided at 29 on one or both extensions, to provide cushioning when they come together.

Figure 4 shows another practical form of human knee joint prosthesis. In general principal the construction is similar to the joint shown in Figure 3.

Connecting means 30, 31 are formed of carbon fibre reinforced epoxy resin and are provided with sockets to receive the femur 32 and tibia 33 respectively, which are pinned in place by pins 34. The connecting means 30, 31 are flexibly joined by a flexible element 35 formed of carbon fibre reinforced polyurethane elastomer. Again the fibre reinforcement is in the form of a combination of unidirectional longitudinally oriented fibres and angled fibres.

The flexible element 35 received and moulded within annular recesses 36 formed in the connecting means 30, 31, and the polyurethane and epoxide materials are co-polymerised in a transition region adjacent these recesses.

Extension 37, 38 of the connecting means 30, 31 come together at 39 to limit the forward flexure of the joint.

In order to inhibit the ingress of body fluids or matter into the joint, including the nipping of any body matter between the connecting means at 39, there is provided a flexible gaiter 40 having elastic sealing rings 41, 42 which are received under tension within annular grooves 43, 44 formed in the outer surfaces of the connecting means 30, 31.

As an important alternative to the arrangement illustrated, in which a clearance is provided at 45 between the two connecting means 40, 41, it may be arranged that these two components make contact at their adjacent surfaces 46, 47. To this end one or both of these surfaces may be curved as shown, to provide a rolling contact. By this means, some or substantially all of the axial load borne by the joint may be transmitted through contact between these surfaces 45, 46.

In Figure 5 there is shown a detail of a modified form of a joint such as that described with reference to Figure 3. In this modification, integral pivot arms 50, 51 are provided on one or both sides of each connecting means 52, 52, and these arms are pivoted together by a pivot pin 54 extending therethrough transversely of the knee joint so as still to permit normal bending. As with previously described embodiments, the connecting means 52, 53 are joined by a flexible element 55 of fibre reinforced elastomer, including a large proportion of longitudinal fibres. The flexible element has high axial stiffeners, and may be placed under pre-compression, so that in any case it carries most of the axial loading on the joint. The purpose of the pivotal connections is to act as locating means, to ensure that the two connecting means 50, 51 remain at all times in proper alignment, especially where extensions such as 26, 27 (Figure 3) are provided, so that proper registration occurs between such extensions.

In Figure 6 there is shown a detail modification of the Figure 5 arrangement. In this case, pivot arms 60, 61 are pivoted together by a pivot pin 62. The pivot arms themselves are provided with co-operating faces 63, 64 which interact as a detent to limit forward bending of the joint.

In Figure 7 there is shown another detail

modification of the Figure 5 arrangement. In this example, pivot arms 70, 71 are pivoted together by a pin 72. The pivot arms are provided with a different arrangement of co-operating faces 73, 74 which interact to limit forward bending.

From the foregoing description and examples, it will be apparent that joints in accordance with the invention can virtually eliminate the corrosion and wear which have posed difficulty in the case of conventional prosthesis joints. They possess the distinct further advantages of low weight, no bearing lubrication required, and use materials which are entirely compatible with body chemistry.

## CLAIMS

1. A joint prosthesis comprising first and second connecting means by which the joint can be rigidly attached to the natural bones which are to be connected by the joint prosthesis, the first and second connecting means being joined together by a flexible element formed of fibre reinforced elastomer.

2. A joint prosthesis according to claim 1 wherein the connecting means are each provided with a socket adapted to receive the end of the natural bone.

3. A joint prosthesis according to claim 2 wherein, in use, the bone is held firmly in position in the socket by means of pins passing transversely through the socket into the bone.

4. A joint prosthesis according to any one preceding claim, wherein the connecting means are of a relatively stiff polymeric material.

5. A joint prosthesis according to claim 4 wherein the elastomer of the flexible element and the polymeric material of the the connecting means are co-polymerised within transition regions linking these components.

6. A joint prosthesis according to claim 4 or 5 wherein the polymeric material incorporates reinforcing fibres.

7. A joint prosthesis according to claim 6 wherein there is continuity of the fibre reinforcement from the flexible element into the connecting means.

8. A joint prosthesis according to any one preceding claim wherein the elastomer material is selected from the group comprising polyurethanes, silicone elastomers, natural rubber, polyisoprene, styrene butadiene, butadiene, polyacrylics, isobutene, isoprene (butyl rubber), chloroprene (neoprene), nitrile butadiene, chlorosulphonated polyethylene, chlorinated polyethylene, ethylene propylene, fluorocarbons, epichlorohydrin, fluorosilicones, co-polyesters, styrene co-polymers and olefins.

9. A joint prosthesis according to any one preceding claim wherein the polymeric material for the connecting means is stiffer than the elastomeric material, and is selected from the group comprising epoxy resins, polyester resins, phenolic resins, vinyl esters, polyamides and polyimides.

10. A joint prosthesis according to claim 9 wherein there is selected a polyurethane as the elastomeric material together with an epoxy resin material for the connecting means.

11. A joint prosthesis according to any one preceding claim including fibres for reinforcement of the elastomer and/or the polymeric material of the connecting means, the fibres being selected from the group comprising fibres of carbon, boron, glass, nylon, polyester, polyimides, aromatic polyamides metals and mixtures of fibres of these materials.

12. A joint prosthesis according to any one preceding claim wherein the connecting means are provided with co-operating detent portions which interact so as to limit the angle through which the joint can be flexed in one or more directions.

13. A joint prosthesis according to claim 12 wherein locating means are provided so as to ensure proper registration between the co-operating detent portions.

14. A joint prosthesis according to any one preceding claim wherein a major proportion of the reinforcing fibres within the elastomer of the flexible element are aligned longitudinally in the line of load transfer through the joint from one connecting means to the other.

15. A joint prosthesis according to claim 14 wherein a minor proportion of the reinforcing fibers are aligned at a substantial angle to the longitudinal axis.

16. A joint prosthesis according to claim 15 wherein the said substantial angle is in the range ±30° to ±60°.

17. A joint prosthesis according to claim 16 wherein the said substantial angle is about ±45°.

18. A joint prosthesis according to any one of claims 14 to 16 wherein the angled fibres are laid down by braiding or filament winding.

19. A joint prosthesis substantially as hereinbefore described with reference to any one or more of the accompanying drawings.

Printed for Her Majesty's Stationery Office by Courier Press, Leamington Spa. 7/1986. Demand No. 8817356.
Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.